IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

In RE: SERZONE

PRODUCTS LIABILITY LITIGATION

MDL NO. 1477
Hon. Joseph R. Goodwin

Appeal of James Lowell Snodgrass (Docket No. 440)

MEMORANDUM OPINION AND ORDER

By virtue of the Third Amended Settlement Agreement ("Agreement") (Docket Sheet Document # 184), the parties designated the undersigned to review any appeals filed by plaintiffs regarding decisions by the Claims Administrator placing them in certain fund categories pursuant to the Agreement and the Schedule of Payments, which is attached to the Agreement as Exhibit B. The Schedule of Payments describes the objective criteria needed to qualify for recovery under Funds A, B, C and D. Funds A, B and C require a showing of a qualifying medical condition and submission of documents showing that the qualifying medical condition is temporally associated with the use of Serzone®. Funds A, B and C are subcategorized according to specific medical criteria. Fund D is the sole fund category which requires only that the plaintiff "can document that he or she purchased Serzone® or used Serzone®, or alleges that he or she was injured by Serzone® and is not making

a claim for benefits or eligible under Funds A, B or C ...." (# 184, Exhibit B.)

On January 17, 2006, Plaintiff James L. Snodgrass submitted a claim form seeking placement and award within Fund B. On May 25, 2006, the Claims Administrator advised Plaintiff he did not qualify for benefits under any fund. On June 9, 2006, Plaintiff, who is pro se and incarcerated, timely appealed the decision of the Claims Administrator. (# 440.) Bristol-Myers Squibb Company ("BMS") has filed a brief in response to the appeal. (# 487.) The court has carefully considered the submissions of both parties.

Under the Agreement, the undersigned must "review ... all documents submitted to the Claims Administrator (including the completed Claims Form and supporting documentation as well as any documents submitted by BMS) ...." (# 184, p. 14.) Pursuant to the Memorandum Opinion and Order Approving Settlement and Certifying the Settlement Class (# 296) entered by the presiding Multi-District Litigation ("MDL") Judge, Judge Goodwin, the undersigned must set aside the Claims Administrator's award if the factual determination was "clear error." (# 296, p. 49.)

For purposes of the instant appeal, "clear error" has not been defined by the parties or the court. Pursuant to Rule 72(a) of the Federal Rules of Civil Procedure, which governs the review of a magistrate judge's order on a nondispositive matter, a decision shall not be modified or set aside unless it is "clearly erroneous

or contrary to law." In Marks v. Global Mortgage Group, Inc., 218 F.R.D. 492, 495 (S.D. W. Va. 2003), Judge Goodwin observed that "[a] district court should reverse a magistrate judge's decision in a discovery dispute as 'clearly erroneous' only if the district court is left with a definite and firm conviction that a mistake has been made." (Citing Clark v. Milam, 155 F.R.D. 546, 547 (S.D. W. Va. 1994)). In the criminal realm, "plain error" as used in Rule 52(b) of the Federal Rules of Criminal Procedure is defined as affecting "substantial rights." In United States v. Olano, 507 U.S. 725, 733-34 (1993), the United States Supreme Court explained that there must be an error that is "plain," which affects "substantial rights." For an error to affect substantial rights, it must "have affected the outcome of the district court proceedings." Id. at 734. If these conditions are met, the court may exercise its discretion to notice the error, but only if the error "'seriously affect[s] the fairness, integrity or public reputation of judicial proceedings.'" Id. at 736 (quoting United States v. Atkinson, 297 U.S. 157, 160 (1936)).

To recover under Fund B, Plaintiff must submit:

> (1) hospital records from an admission in which treatment for an alleged Serzone®-related liver injury was provided or, if the claimant was not hospitalized, medical records from contemporaneous treatment in which a hepatologist, board certified gastroenterologist or board certified internist stated that the claimant's qualifying liver event was temporally associated with the ingestion of Serzone®; or
> (2) a report from a hepatologist, board certified gastroenterologist or board certified internist, which

> states that the claimant's qualifying liver event was temporally associated with the ingestion of Serzone®.
>
> The claimant must also complete the Fund B General Hepatic Injury Claim Form and provide all documents required by that Form.
>
> "Temporal Association," as used in Fund B, requires the qualifying liver injury to occur within two (2) weeks after last documented use of Serzone®.
>
> "Acute Hepatocellular Injury," as used in Fund B, requires evidence of acute hepatocellular damage documented in a pathology report.

(# 184, Exhibit B.)

The events that qualify Serzone® users for recovery under Fund B "Matrix Levels" are as follows:

> Level B-I: Claimants who developed an acute liver injury, the management or treatment of which required hospitalization, and who developed significant simultaneous elevations of liver enzymes and total bilirubin levels (as defined below) established by two (2) consecutive blood tests separated by at least two (2) days but less than ninety (90) days [footnote omitted] may recover under matrix level B-I. For matrix level B-I, the age at time of qualifying liver event used to determine the appropriate base matrix level is the age on the initial date of hospitalization for the acute liver injury.
>
> For claimants with normal baseline liver enzyme test results [footnote omitted] seeking recovery under matrix level B-I, simultaneous elevations of liver enzymes and total bilirubin levels means that either the claimant had AST and/or ALT levels greater than or equal to fifteen (15) times the upper limit of normal simultaneous with total bilirubin levels greater than or equal to two milligrams per deciliter (2.0 mg/dl), documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total

bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.

For all remaining claimants seeking recovery under matrix level B-I (those with abnormal baseline liver enzyme results), simultaneous elevations of liver enzymes and total bilirubin levels means that either the claimant had AST or/and ALT levels greater than or equal to fifteen (15) times the claimant's average elevated enzyme level prior to his/her initial use of Serzone® simultaneous with total bilirubin levels greater than or equal to two (2) times the claimant's average elevated total bilirubin levels prior to his/her initial use of Serzone® or two milligrams per deciliter (2.0 mg/dl), whichever is greater, documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.

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Level B-II: Claimants who developed an acute liver injury, the management or treatment of which required hospitalization or at least three (3) independent instances of outpatient care, and who developed significant elevations of liver enzymes or total bilirubin levels (as defined below) established by two (2) consecutive blood tests separated by at least two (2) days but less than ninety (90) days [footnote omitted] may recover under matrix level B-II. For matrix level B-II, the age at time of qualifying liver event used to determine the appropriate base matrix level is the age on the initial date of hospitalization or initial office visit for treatment of the acute liver injury.

For claimants with normal baseline liver enzyme test results [footnote omitted] seeking to recover under matrix level B-II, significant elevations of liver enzymes or total bilirubin levels means that the claimant had AST and/or ALT levels greater than or equal to ten (10) times the upper limit of normal or total bilirubin levels greater than or equal to three milligrams per

deciliter (3.0 mg/dl), documented by two (2) consecutive blood tests, each establishing the requisite elevations of AST and/or ALT and/or total bilirubin, separated by at least two (2) days but less than ninety (90) days [footnote omitted].

For all remaining claimants seeking to recover under matrix level B-II (those with abnormal baseline liver enzyme results), significant elevations of liver enzymes or total bilirubin levels means that the claimant had AST and/or ALT levels greater than or equal to ten (10) times the claimant's average elevated enzyme level prior to his/her initial use of Serzone® or total bilirubin levels greater than or equal to three (3) times the claimant's average elevated total bilirubin levels prior to his/her use of Serzone® or three milligrams per deciliter (3.0 mg/dl), whichever is greater, documented by two (2) consecutive blood tests, each establishing the requisite elevations of AST and/or ALT and/or total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted].

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Level B-III: Claimants who developed, and have a contemporaneous diagnosis of, one or more of the qualifying conditions listed below, the management or treatment of which required hospitalization or at least three (3) independent instances of outpatient care for the treatment of the underlying qualifying condition may recover under matrix level B-III. For matrix level B-III, the age at time of qualifying liver event used to determine the appropriate base matrix level is the age on the initial date of hospitalization or initial outpatient visit for the qualifying liver condition.

» Jaundice: Claimants clinically diagnosed with jaundice Temporally Associated with the use of Serzone® and that had total bilirubin levels greater than two milligrams per deciliter (>2.0 mg/d) excluding those claimants who, prior to or during Serzone® use had a Chronic Liver Condition [footnote omitted], an Acute Liver Condition [footnote omitted], Gilbert's syndrome, Rotor's syndrome or Dubin-Johnson syndrome.

» Elevations of Liver Enzymes and Total Bilirubin: Claimants diagnosed with elevated liver enzymes and total

bilirubin levels in temporal association with their use of Serzone®.

For claimants with normal baseline liver enzyme test results [footnote omitted] seeking recovery under matrix level B-III, simultaneous elevations of liver enzymes and total bilirubin levels means that either the claimant had AST and/or ALT levels greater than or equal to five (5) times the upper limit of normal simultaneous with total bilirubin levels greater than or equal to one and one-half milligrams per deciliter (1.5 mg/dl), documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.

For all remaining claimants seeking recovery under matrix level B-III (those with abnormal baseline liver enzyme results), simultaneous elevations of liver enzymes and total bilirubin levels means that either the claimant had AST or/and ALT levels greater than or equal to five (5) times the claimant's average elevated enzyme level prior to his/her initial use of Serzone® simultaneous with total bilirubin levels greater than or equal to one and one-half milligrams per deciliter (1.5 mg/dl) or fifty (50) percent greater than the claimant's average elevated total bilirubin levels prior to his/her initial use of Serzone®, whichever is greater, documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.

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Level B-IV: Claimants who developed slight simultaneous elevations of liver enzymes and total bilirubin levels (as defined below) established by two (2) consecutive blood tests separated by at least two (2) days but less than ninety (90) days [footnote omitted] may recover

> under matrix level B-IV. For matrix level B-IV, the age at time of qualifying liver event used to determine the appropriate base matrix level is the age on the date of the initial blood test revealing elevations in liver enzymes and total bilirubin.
>
> For claimants with normal baseline liver enzyme test results [footnote omitted] seeking recovery under matrix level B-IV, slight simultaneous elevations of liver enzymes and total bilirubin levels means that either the claimant had AST and/or ALT levels greater than or equal to two (2) times the upper limit of normal simultaneous with abnormal and elevated total bilirubin test levels, documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.
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> For all other claimants seeking recovery under matrix level B-IV (those with abnormal baseline liver enzyme results), slight simultaneous elevations of liver enzymes means that either the claimant had AST and/or ALT levels greater than or equal to two (2) times the claimant's average enzyme level prior to his/her initial use of Serzone® simultaneous with abnormal and elevated total bilirubin levels, compared to his/her levels prior to initial Serzone® use, documented by two (2) consecutive blood tests, each establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels, separated by at least two (2) days but less than ninety (90) days [footnote omitted], or one (1) blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of Acute Hepatocellular Injury.

(# 184, Exhibit B.)

To recover under Fund C, Plaintiff must submit:

> (1) hospital records from an admission in which treatment for an alleged Serzone® related liver injury was provided

> or, if claimant was not hospitalized, medical records from contemporaneous treatment in which a licensed medical physician stated that the claimant's qualifying liver injury was temporally associated with the ingestion of Serzone®; or
> (2) a report from a hepatologist, board certified gastroenterologist or board certified internist, which states that the claimant's qualifying liver injury was temporally associated with the ingestion of Serzone®.
>
> The claimant must also complete the Fund C Non-Serious Hepatic Injury Claim Form and provide all documents required by that Form.
>
> To qualify under Fund C, the claimant must provide documented evidence of elevated liver enzymes or total bilirubin levels in Temporal Association with the use of Serzone®.
>
> "Temporal Association," as used in Fund C, requires the qualifying liver injury to occur within two (2) weeks after last documented use of Serzone®.

(# 184, Exhibit B.) To recover under Level C-I, claimants with normal baseline liver enzyme test results must show "AST or ALT levels greater than or equal to three (3) times the upper limit of normal" or "total bilirubin levels greater than or equal to two milligrams per deciliter (2.0 mg/dl)." (# 184, Exhibit B.) Claimants with abnormal baseline liver enzyme results must show "AST or ALT levels greater than or equal to three (3) times the claimant's average liver enzyme levels prior to his/her initial use of Serzone®" or "total bilirubin levels greater than or equal [to] two (2) times the claimant's average total bilirubin level prior to his/her initial use of Serzone® or two milligrams per deciliter (2.0 mg/dl), whichever is greater." (# 184, Exhibit B.)

To recover under Level C-II, claimants with normal baseline liver enzyme test results must show "AST or ALT or total bilirubin levels fifty percent (50%) greater than the claimant's average liver enzyme or total bilirubin levels prior to his/her initial use of Serzone®." (# 184, Exhibit B.) For those with abnormal baseline liver enzyme results, claimants must show "AST or ALT or total bilirubin levels fifty percent (50%) greater than the claimant's average liver enzyme or total bilirubin levels prior to his/her initial use of Serzone®." (# 184, Exhibit B.)

To recover under Fund D, claimant must "document that he or she purchased Serzone® or used Serzone®, or [allege] that he or she was injured by Serzone® and is not making a claim for benefits or eligible for benefits under Funds A, B or C." (# 184, Exhibit B.)

In his appeal, Plaintiff asserts that the Claims Administrator did not consider all of the evidence submitted by him in making the decision that he did not qualify for placement in any fund. (# 440.) Plaintiff does not identify the evidence to which he refers.

In response, BMS argues that the Plaintiff fails to qualify under Funds B or D. Regarding Fund D in particular, BMS asserts that Plaintiff "failed to provide any information to show purchase or use of Serzone®." (# 487, p. 3.)

Plaintiff submitted no medical evidence, but does assert on an Inventory Form that he believes he developed a known physical injury as a result of the use of Serzone®.

Although Plaintiff does not qualify for placement in Funds B or C, the court finds, by the plain language of the Schedule of Payments, that Plaintiff qualifies for placement in Fund D. In its brief, BMS asserts that Plaintiff does not qualify for an award under Fund D because he failed to provide proof of use or purchase of Serzone®. BMS does not address the fact that Fund D contains two additional avenues for a Fund D award. The Schedule of Payments explicitly provides that if the claimant (1) alleges that he or she was injured by Serzone® and is not making a claim for benefits; or (2) alleges that he or she was injured by Serzone® and is not eligible for benefits under Funds A, B, or C, the claimant may make a claim for benefits under Fund D. (# 184, Exhibit B.) In light of Plaintiff's allegation on the Inventory Form that he believes he developed a known physical injury as a result of the use of Serzone® and the fact that Plaintiff does not qualify for benefits under Funds A, B or C, Plaintiff has qualified for an award under the final avenue provided for in Fund D. Thus, the court finds the decision of the Claims Administrator placing Plaintiff in no fund was clear error. Instead, Plaintiff has met the requirements for placement in Fund D.

Accordingly, it is hereby **ORDERED** that Plaintiff's appeal is **DENIED** to the extent he seeks placement in Fund B, but **GRANTED** insofar as Plaintiff should be placed in Fund D.

The Clerk is directed to transmit a copy of this Memorandum Opinion and Order to Plaintiff, counsel of record and the Claims Administrator.

ENTER: July 18, 2006

Mary E. Stanley
Mary E. Stanley
United States Magistrate Judge